REMARKS

STATUS OF CLAIMS

Claims 54, 57, 66, and 69 are objected to only as dependent on rejected claims. All other claims are rejected over newly cited references. Applicants appreciate the withdrawal of the rejections for lack of written description and new matter in view of the amendment to the claims. Applicants further appreciate the withdrawal of the rejections over Schatz and Barbas.

THE AMENDMENTS

The claims have been amended so that each claim now recites that the cellular protein which is detected (a) is a cellular protein on the surface of a cell, and (b) that the detection of the protein occurs on the cell. These amendments are fully supported and do not add new matter to the application. Support for the amendment can be found throughout the application. For example, Figures 3A, 3B, 4C, and 5A-5C depict detection on the surface of cells. At page 6, line 8 and following, the applicants teach that a sample "is not an isolated polypeptide." Moreover, at page 6, line 14, the applicants specifically teach that the protein detected can be *inter alia* a surface protein. Applicants further teach at page 8, line 18, that the detectable viruses of the invention can be used to detect "the presence of a selected cellular protein on the surface of a cell."

REJECTION OF CLAIMS 1, 5, 9, 45-51, 53, 55-56, 67-68, 70-72 UNDER 35 U.S.C. §102(b)

Maruyama (U.S. 5,627,024) is cited as anticipating claims 1, 5, 9, 45-51, 53, 55-56, 67-68, 70-72.

In order to find anticipation, each and every element set forth in the claim must be

found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). Maruyama does not teach each element and thus fails to anticipate the claims.

The rejected claims recite:

- a ligand for a selected cellular protein on the surface of a cell,
- detecting binding of the virus to the cell.

First, Maruyama does not teach a ligand for a protein on the surface of a cell. Maruyama teaches the expression by bacteriophage of β-galactosidase and BPA, a plant lectin from *Bauhinia purpurea*. Neither is a ligand for a cell surface protein. β-galactosidase is a tetramer of 465 kDa that binds to and cleaves certain sugars, not to proteins on the surface of a cell. BPA is a tetramer of 120 kDa that binds to mucin with a very low affinity (10^{-1} M). Column 12, lines 36-39. Mucins form a family of proteins, some of which are secreted proteins. The mucin taught by Maruyama is Type 1 or Type 1S from bovine submaxillary glands, as sold by Sigma (specification sheets attached). As indicated on the specification sheets, this protein is found in mucus, ("albuminoid substance in mucus which gives it its ropy consistency"), and thus is a secreted protein.

Second, Maruyama does not teach detecting binding of a virus to a cell. Maruyama does not describe any assays where cells were detected using the recombinant viruses to bind to cell surface proteins. The functions which Maruyama teaches for his recombinant viruses are enzymatic activity and binding to an artificial solid phase coated with protein. At column 58, lines 10-33, Maruyama teaches that the β-galactosidase phage displayed enzymatic activity, *i.e.,* they could cleave a galactoside sugar to two component sugars. There is no indication that the galactoside sugar substrate is on a cell surface. Maruyama's recombinant

viruses which express BPA fusions were used in an ELISA format in which microtiter wells were coated with mucin. See column 61, lines 34-56. In no case does Maruyama teach that the recombinant viruses can detect proteins on the surface of a cell.

Thus Maruyama fails to teach at least two elements of the claims. Therefore Maruyama cannot anticipate the rejected claims.

REJECTION OF CLAIMS 1, 5, 9, 17, 22, 45-51, 53-56, 58-65, 67-68, and 70-75 UNDER 35 U.S.C. §103(a)

The enumerated claims are rejected as unpatentable over a combination of Maruyama (U.S. 5,627,024) and Mattheakis (U.S. 5,922,545).

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. The rejection of the enumerated claims over Maruyama and Mattheakis fails to make a *prima facie* case because the prior art references fail to teach or suggest all the claim limitations.

Each of the rejected claims recites:

- a ligand for a selected cellular protein on the surface of a cell,
- detecting binding of the virus to the cell.

As detailed above, Maruyama does not teach these elements of the claimed methods. Mattheakis does not remedy these deficiencies. Mattheakis is cited by the Patent Office

merely to teach filamentous phage particles and the use of coat protein pVIII. This teaching clearly does not remedy the deficiency of Maruyama in teaching an assay which detects a cell by detecting the presence of a surface protein on the cell surface. Since neither reference teaches these elements, the combination of references *per force* fails to teach these elements. On this basis alone the rejection fails to meet the Patent Office's own requirements for making a *prima facie* case. In view of this failure, the rejection should be withdrawn.

Moreover, the prior art does not provide a reasonable expectation of success that recombinant viruses expressing such a ligand could successfully bind to cells. Prior to the present invention it would not have been reasonably expectable that a ligand expressed on a recombinant virus would be sterically accessible to a protein on a cell's surface. Interactions between the virus particle and the cell surface, either physical or chemical, could have inhibited the ligand's successful accessing of the cell surface protein. Thus, those of skill in the art would not have had a reasonable expectation of success that recombinant viruses expressing ligands on their surfaces could be used to detect cells expressing cell surface proteins on their surfaces. The teachings of the cited prior art would have done nothing to provide those of skill in the art with a reasonable expectation of success.

CONCLUSION

All rejections having been addressed, applicant respectfully submits that the instant application is in condition for allowance, and respectfully solicits prompt notification of the same.

Respectfully submitted,

Dated: September 27, 2005

By: _____
Sarah A. Kagan
Registration No. 32,141

Banner & Witcoff, Ltd.
Customer No. 22907

M3895 Mucin from bovine submaxillary glands

Sigma **Type I-S**

CAS Number	84195-52-8
EG/EC Number	2823574
MDL number	MFCD00131629

Expand/Collapse All

Price and Availability

Click For Pricing and Availability

Descriptions

Biochem/physiol Actions	Albuminoid substance in mucus which gives it its ropy consistency
Linkage	Similar to M 4503, but produced by Sigma.
Substrates	Neuraminidase substrate.

Properties

composition	Bound sialic acids9-17%
storage temp.	−20°C

Safety

F	10

Related Categories

... Extracellular Matrix > **Extracellular Matrix Peptides and Proteins**

M4503 Mucin from bovine submaxillary glands

Sigma **Type I**

CAS Number	84195-52-8
EG/EC Number	2823574
MDL number	MFCD00131629

Expand/Collapse All

Price and Availability

Click For Pricing and Availability

Descriptions

Biochem/physiol Actions	Albuminoid substance in mucus which gives it its ropy consistency
Substrates	Neuraminidase substrate.

Properties

composition	Bound sialic acids, ~5%
storage temp.	−20°C

References

Reference Nisizawa, K. and Pigman, W. *Arch. Oral Biol.* **1**, 161, (1959)

Safety

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